Citation:

Avenell A, Brown TJ, McGee MA, Campbell MK, Grant AM, Broom J, Jung RT, Smith WC. What are the long-term benefits of weight reducing diets in adults? A systematic review of randomized controlled trials. J Hum Nutr Diet. 2004 Aug;17(4):317-35.

PubMed ID: 15250842

Study Design:

Systematic Review

Class:

M - <u>Click here</u> for explanation of classification scheme.

Research Design and Implementation Rating:



POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

This review examines the effectiveness of weight reducing diets over at least 1 year of follow-up, in comparison with no active treatment or against each other.

Inclusion Criteria:

- 13 electronic databases were searched including MEDLINE, EMBASE, CAB abstracts, The Cochrane Central Register of Controlled Trials (CENTRAL) and PsycINFO (earliest date 1966 to May 2001) for randomized controlled trials (RCTs) and systematic reviews of RCTs.
- Weight loss studies (LCD, low calorie diet; VLCD, very low calorie diet) discussed had an initial period of weight loss followed by attempts at weight maintenance (the distinction between the two phases was rarely made by the investigators).
- Included RCTs had to have a mean or median duration of 52 weeks or over for all groups, from the point of randomization.
- The mean or median age for all groups had to be 18 years or over with a minimum mean or median BMI of 28 kg/m².
- English language articles only.

Exclusion Criteria:

Article exclusion criteria not specifically mentioned.

Description of Study Protocol:

Recruitment

The authors searched 13 electronic databases including MEDLINE, EMBASE, CAB abstracts, The Cochrane Central Register of Controlled Trials (CENTRAL) and PsycINFO (earliest date 1966 to May 2001) for randomized controlled trials (RCTs) and systematic reviews of RCTs

Design: Systematic review

Blinding used (if applicable): not applicable

Intervention (if applicable)

Studies included in the review includes low calorie diet [LCD (4.2–6.7 MJ day)], very low calorie diet [VLCD(<4.2 MJ day)], Low fat diet (LFD), Protein sparing modified fast (PSMF): where carbohydrate content was ≤ 40 g day), irrespective of energy content.

Statistical Analysis

• A statistical meta-analysis of the data was used to determine the typical effect size of the intervention. For continuous data a weighted mean difference (WMD) was calculated (weighted by the inverse of the variance). Evidence of heterogeneity across studies was explored using the Chi-squared test for heterogeneity.

- Weight or risk factors were presented as actual values rather than changes, differences were calculated by subtraction of the endpoint value from the value at time of randomization.
- A linear regression was made of the SD of the mean change in weight on the absolute mean change for weight.

Data Collection Summary:

Timing of Measurements: not applicable

Dependent Variables

- Mortality
- Morbidity
- Quality of life
- Economic outcomes
- Weight changes
- Cardiovascular risk factors: total cholesterol, low density cholesterol (LDL), high density cholesterol (HDL), triglycerides (TGs), systolic and diastolic blood pressure (SBP and DBP)
- Fasting glucose and glycosylated haemoglobin (HbA1c)
- Drop-outs
- Adverse events

Independent Variables

- Low calorie diet [LCD (4.2–6.7 MJ day)]
- Very low calorie diet [VLCD (<4.2 MJ day)]
- Low fat diet (LFD)
- Protein sparing modified fast (PSMF): where carbohydrate content was ≤ 40 g day)

Control Variables

Description of Actual Data Sample:

Initial N:

32,725 reports of studies from 13 databases reviewed (26 RCTs)

Attrition (final N):

2,163 reports of possible RCTs obtained full details (17 RCTs included men and women)

Age:

Age varies from 30-60 yrs

Ethnicity: not reported

Other relevant demographics:

Anthropometrics

Location: USA and Europe

Summary of Results:

Key Findings

- 32,725 reports of studies from 13 databases reviewed.
- 2163 reports of possible RCTs obtained full details.
- 26 RCTs compared LFDs, LCDs or VLCDs with control treatment, or compared different kinds of diet.
- No RCTs comparing PSMFs to control treatment, although these diets were compared with LCDs and VLCDs.
- Ten of the RCTs had a follow-up period of only 12 months, and the longest follow-up was approximately 5 years.
- Fourteen of the trials recruited participants with concomitant medical conditions, such as hypertension, impaired glucose tolerance, type 2 diabetes, myocardial infarction, breast cancer and asthma.
- Seventeen of the 26 RCTs included both men and women.
- Only one trial included groups with mean BMI over 40 kg m)2, and only six other RCTs had groups with mean BMI over 35 kg m².
- Seventeen of the RCTs took place in the USA.
- Four of the RCTs assessed only weight change as the outcome of interest in the study.
- Three RCTs assessed quality of life. Changes in cardiac risk factors were rarely assessed after the first 12 months of a study.
- The weighted mean difference weight change at 12 months was -5.31 kg in favour of LFDs (95% CI, -5.86 kg to -4.77 kg).
- There was evidence of statistical heterogeneity, although the direction of effect was consistent across all studies (P < 0.00001).
- When 12 month weight changes from studies with imputed values were compared with studies with no assumed values, the weight changes were -4.80 kg (95% CI, -6.02 to -3.57 kg) compared with -5.44 kg (95% CI, -6.04 to -4.84 kg).
- When 12 month weight loss from RCTs with participants with cardiovascular risk factors were compared with RCTs with participants with no reported risk factors, a clearer difference between studies emerged (-4.20 kg, 95% CI, -4.90 to -3.50 kg; compared with -6.98 kg, 95% CI, -7.83 to -6.12 kg, respectively).
- At 12 months diastolic and systolic blood pressure, lipids and fasting plasma glucose were all significantly improved compared with the control groups.
- The limited data after 12 months no longer showed statistically significant risk factor changes.
- Compared with the control group, the LCD was associated with a weighted mean difference weight change at 12 months of -6.25 kg (95% CI, -9.05 to -3.45 kg).
- In the cluster RCT, weight change at 12 months was)0.88 kg (SD: 4.0 kg) for the diet group and 1.3 kg (SD: 3.00 kg) for the control group, which was not found to be a statistically significant difference.
- Blood pressure, lipids and fasting plasma glucose improved with these diets after 12 months. Four studies found that LFDs may prevent type 2 diabetes and reduce antihypertensive medication for up to 3 years.
- A very low calorie diet (VLCD, <4.2 MJ day)1) was associated with the most weight loss after 12 months (-13.40 kg; 95% CI, -18.43 to -8.37 kg) in one small study with beneficial effects on asthma.
- There was no evidence that low carbohydrate protein sparing modified fasts (PSMFs) were associated with greater long-term weight loss than low calorie diets (LCDs, 4.2–6.7 MJ day)1) or VLCDs.
- At 18 months the difference in weight change was -1.15 kg (95% CI, -2.76 to 0.45 kg), 24 months -2.35 kg (-3.56 to -1.15 kg), 30 months 0.70 kg (95% CI, -1.78 to 3.18 kg), 36 months -3.55 kg (95% CI, -4.54 to -2.55 kg), and at 60 months -0.20 kg (95% CI, -2.03 to 1.63 kg).
- At 12 months the VLCD compared with control was associated with a weighted mean difference weight change of -13.40 kg (95% CI, -18.43 to -8.37 kg).
- After 12 months the difference in forced expiratory volume in one second between VLCD and control groups was 7.6% (95% CI, 1.5 to 13.8%), forced vital capacity 7.6% (95% CI, 3.5 to 11.8%) and peak expiratory flow 6.2% (95% CI,)1.4 to 13.7%).
- PSMFs were, however, associated with greater lowering of fasting plasma glucose and HbA1c than LCDs.
- At 24 months difference in weight change was- 7.00 kg (95% CI, -10.99 to -3.01 kg) and at 36 months was -6.10 kg (95% CI, -10.71 to -1.49 kg).
- Three breast cancers occurred in the intervention group and one in the control group. Three people died from breast cancer in the intervention group and five people in the control group. There were two deaths from other causes in each of the two groups.
- At 12 months PSMFs compared with LCDs were associated with a weight change of -3.57 kg (95% CI,-7.36 to 0.22 kg), at 18 months of 0.69 kg (95% CI, -1.58 to 2.96 kg), at 24 months of-2.17 kg (95% CI,-4.88 to 0.54 kg), at 36 months of -1.51 kg (95% CI, -5.43 to 2.41 kg), and at 60 months of 0.20 kg (95% CI, -5.68 to 6.08 kg).
- LFDs were associated with significant weight losses at 12, 24 and 36 months compared with control treatment. There was an associated improvement in blood pressure, lipids and fasting plasma glucose with these diets at 12 months.

- Very limited data on risk factors after 12 months were available, with a trend for blood pressure to be decreased by these diets at 36 months.
- The median number of exacerbations per person was 1 (range: 0–7) in the control group and 1 (range 0–4) in the VLCD group (reported P < 0.001).
- One RCT compared a LCD with a LFD and found , no evidence of a significant difference in weight: weight change of 1.63 kg (95% CI, -1.26 to 4.52 kg) .
- Eight of the ten participants in the VLCD group and two of the six participants in the low fat group were treated for their diabetes by diet only before the trial commenced.
- At 24 months the trial observed a non-significant weight change of -4.70 kg (95% CI, -11.79 to 2.39) in favour of VLCD.
- Four RCTs compared VLCDs with LCDs, compared to LCDs, VLCDs were associated with an overall non-significant difference in weight change at 12 months of -0.15 kg (95% CI, -2.73 to 2.43 kg), and at 18 months of -1.13 kg (95% CI, -5.32 to 3.06 kg).
- Seven RCTs provided change in weight at 12 months or longer, including a total of 480 participants.
- At 18 months PSMF compared with VLCD was associated with a weighted mean difference weight change of 2.73 kg (95% CI, 0.07 to 5.39 kg).
- No risk factor data were available to allow comparisons between LCDs and LFDs.
- No risk factor changes were also available for VLCDs compared with no treatment.

Author Conclusion:

Little evidence supports the use of diets other than LFDs for weight reduction. With the increasing prevalence of morbid obesity, long-term follow-up in RCTs is needed to evaluate the effect of LCDs, VLCDs and PSMFs more fully.

Reviewer Comments:

- Only LFD studies provide significant information and studies are limited for other diets.
- It is also important to review the physical exercise and behavioral interventions along with diets to focus in future studies.

Research Design and Implementation Criteria Checklist: Review Articles

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Relevan	ce Questions	
1.	Will the answer if true, have a direct bearing on the health of patients?	Yes
2.	Is the outcome or topic something that patients/clients/population groups would care about?	Yes
3.	Is the problem addressed in the review one that is relevant to nutrition or dietetics practice?	Yes
4.	Will the information, if true, require a change in practice?	Yes

Validity Questions

Was the question for the review clearly focused and appropriate?
Was the search strategy used to locate relevant studies comprehensive? Were

the databases searched and the search terms used described?

3.	Were explicit methods used to select studies to include in the review? Were inclusion/exclusion criteria specified and appropriate? Were selection methods unbiased?	Yes
4.	Was there an appraisal of the quality and validity of studies included in the review? Were appraisal methods specified, appropriate, and reproducible?	Yes
5.	Were specific treatments/interventions/exposures described? Were treatments similar enough to be combined?	Yes
6.	Was the outcome of interest clearly indicated? Were other potential harms and benefits considered?	Yes
7.	Were processes for data abstraction, synthesis, and analysis described? Were they applied consistently across studies and groups? Was there appropriate use of qualitative and/or quantitative synthesis? Was variation in findings among studies analyzed? Were heterogeneity issued considered? If data from studies were aggregated for meta-analysis, was the procedure described?	Yes
8.	Are the results clearly presented in narrative and/or quantitative terms? If summary statistics are used, are levels of significance and/or confidence intervals included?	Yes
9.	Are conclusions supported by results with biases and limitations taken into consideration? Are limitations of the review identified and discussed?	Yes
10.	Was bias due to the review's funding or sponsorship unlikely?	Yes

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